STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Human Services
DIVISION OF HEALTH CARE QUALITY,
FINANCING AND PURCHASING
Center For Child and Family Health
600 New London Avenue
Cranston, Rhode Island 02920
Telephone: 462-2501 Fax: 462-6353

RIte Care

1/13/2006

TO: Gilson DaSilva (BCBSRI)
Ron Barnett (NHPRI)
Patrice Cooper (UHC)

FROM: Tricia Leddy
Administrator, Center for Child and Family Health

SUBJECT: RIte Care Health Plan Contract Benefits Clarification: Humanitarian Use Devices (HUDs)

Background: On 06/26/1996, the U.S. Food and Drug Administration (FDA) issued a final rule to carry out provisions of the Safe Medical Devices Act of 1990 regarding humanitarian use devices (HUDs). This regulation became effective on 10/24/1996. A HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year.

The FDA's materials pertaining to HUDs are attached to this memorandum. The attachment also includes a listing of approved HUDs.

Benefits Clarification: The Social Security Act (SSA) specifically prohibits Medicaid coverage of experimental drugs or procedures. Humanitarian use devices that have been approved by the FDA are not considered experimental. Medically necessary FDA approved HUDs are Medicaid covered and an in-plan capitated RIte Care benefit.

Please do not hesitate to contact me if there are any questions.

cc: Deborah Florio
Rick Jacobsen
Lissa DiMauro
Murray Brown

ATTACHMENT

Humanitarian Use Devices

See Related Information

- General Information
- Listing of CDRH Humanitarian Device Exemption Summaries of Safety and Possible Benefit
- Other Resources

General Information

On June 26, 1996, FDA issued a final rule to carry out provisions of the Safe Medical Devices Act of 1990 regarding humanitarian use devices (HUDs). This regulation became effective on October 24, 1996. An HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. A device manufacturer's research and development costs could exceed its market returns for diseases or conditions affecting small patient populations. FDA, therefore, developed and published this regulation to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

The regulation provides for the submission of an humanitarian device exemption (HDE) application, which is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.

An approved HDE authorizes marketing of the HUD. However, an HUD may only be used after IRB approval has been obtained for the use of the device for the FDA approved indication. The labeling for an HUD must state that the device is an humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

Listing of CDRH Humanitarian Device Exemption Summaries of Safety and Possible Benefit

HDE Number Approval Date and DocketNumber	Device Name	Company Name and Address	Device Description/Device Indications

H050001 03-Aug-2005 05M-0308	Wingspan Stent System with Gateway PTA Balloon Catheter	Boston Scientific Smart	This device is indicated for improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with greater than or equal to 50% stenosis that are accessible to the system.
H030005 30-Mar-2005 05M-0132	CoAxia NeuroFlo Catheter	CoAxia, Inc.	This device is indicated for the treatment of cerebral ischemia resulting from symptomatic vasospasm following aneurismal subarachnoid hemorrhage, secured by either surgical or endovascular intervention for patients who have failed maximal medical management.
H030009 24-Aug-2004 04M-0415	Vertical Expandable Prosthetic Titanium Rib (VEPTR)	Synthes (USA)	For the treatment of Thoracic Insufficiency Syndrome (TIS) in skeletally immature patients. TIS is defined as the inability of the thorax to support normal respiration or lung growth. For the purpose of identifying potential TIS patients, the categories in which TIS patients fall are as follows: Flail Chest Syndrome Rib fusion and scoliosis Hypoplastic thorax syndrome, including • Jeune's syndrome • Achondroplasia • Jarcho-Levin syndrome • Ellis van Creveld syndrome

H020008 07-Apr-2004 04M-0165	OP-1 Putty	Stryker Biotech 35 South Street Hopkinton, MA 01748	For use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion. Examples of compromising factors include osteoporosis, smoking and diabetes.
H030003 25-Feb-2004 04M-0090	DeBakey VAD Child Left Ventricular Assist System	MicroMed Technology, Inc.	For use to provide temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5-16 years old, with BSA>= 0.7 m^2 and <1.5 m^2) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are (listed) candidates for cardiac transplantation.
H030004 24-Feb-2004 04M-0084	Heartsbreath	Menssana Research Inc. 1 Horizon Road Suite 1415 Fort Lee, NJ 07024-6510 USA	For use as an aid in the diagnosis of grade 3 heart transplant rejection in patients who have received heart transplants within the preceding year. The Heartsbreath test is intended to be used as an adjunct to, and not as a substitute for, endomyocardial biopsy. The use of the device is limited to patients who have had endomyocardial biopsy within the previous month.
H020003 21-Nov-2003 03M-0536	CONTEGRA Pulmonary Valved Conduit	Medtronic, Inc	The CONTEGRA Pulmonary Valved Conduit is indicated for correction or

			reconstruction of the Right Ventricular Outflow Tract (RVOT) in patients aged less than 18 years with any of the following congenital heart malformations: • Pulmonary Stenosis • Tetralogy of Fallot • Truncus Arteriosus • Transposition with Ventricular Septal Defect (VSD) • Pulmonary Atresia In addition, the conduit is indicated for the replacement of previously implanted, but dysfunctional, pulmonary homografts or valved conduits.
H020004 07-Jul-2003 03M-0305	Dermagraft	Smith and Nephew Wound Management	For use in the treatment of wounds associated with Dystrophic Epidermolysis Bullosa (EB).
H020007 15-Apr-2003 03M-0157	Medtronic Activa Dystonia Therapy	Medtronic Neurological	For unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in patients seven years of age or above
H020002 02-Sep-2002 02M-0409	Neuroform Microdelivery Stent System	SMART Therapeutics, Inc. 2551 Merced St. San Leandro,	The Neuroform Microdelivery Stent System is intended for use with embolic coils for the treatment of wide neck, intracranial, saccular

		CA 94577 USA	aneurysms arising from a parent vessel with a diameter of greater than or equal to 2mm and less than or equal to 4.5mm that are not amenable to treatment with surgical clipping. Wide neck aneurysms are defined as having a neck of 4mm or a dome-to-neck ratio of <2.
H010004 09-Aug-2002 02M-0361	NEUROLINK® System, including NEUROLINK® Stent & Delivery Catheter and NEUROLINK® Balloon Dilatation Catheter	Guidant Corporation Santa Clara, CA USA	The NEUROLINK® System is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with > 50% stenosis and that are accessible to the stent system
H000007 05-Apr-2002 02M-0167	Amplatzer® PFO Occluder	AGA Medical Corporation Golden Valley, MN	For the non-surgical closure of a patent foramen ovale (PFO) in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy.
H010005 22-Mar-2002 02M-0121	Ascension® PIP	Ascension Orthopedics, Inc. Austin, TX	For use in arthroplasty of the proximal interphalangeal (PIP) joint when the patients has soft tissue and bone that can provide adequate stabilization and fixation under high demand loading conditions after reconstruction; and needs a revision of a failed PIP prostheis, or has pain, limited motion, or joint subluxation/dislocation secondary to damage or

			destruction of the articular cartilage.
H000002 19-Dec-2001 02M-0311	VISX Excimer Laser System and Custom Contoured Ablation Pattern (C-CAP) Method™	VISX, Inc.	For the treatment of asymmetrical ablation patterns from previous laser refractive surgery caused by decentration of the treatment as viewed on the Zeiss Humphrey® topography unit and treated with the STAR S3 ActiveTrak™ Excimer Laser System in patients: • who exhibit symptomatology supportive of visual defect: reduced best spectacle-corrected visual acuity, debilitating glare, monocular diplopia (double vision), and/or debilitating halos; and, • who pre-operatively have at least a 6 µm difference on the elevation topography, from the lowest point to the highest point, over a 6.5 mm diameter or over the patient's pupil diameter as measured by the Zeiss Humphrey topographer, whichever is larger
H010002 17-Oct-2001 01M-0482	OP-1™ Implant	Stryker Biotech Hopkinton, MA	The device is indicated for use as an alternative to autograph in recalcitrant long bone nonunions where use of autograph is unfeasible and alternative treatments have failed.
H010001	Avanta	Avanta	The device is indicated for

28-Aug-2001 01M-0392	Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis	Orthopaedics, Inc. San Diego, CA	use in arthroplasty of the MCP joint when either the: 1. patient is in need of a revision of failed MCP prosthesis(es); or 2. patient expects to place his/her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic MCP joint.
H000004 19-Mar-2001 01M-0485	PROSTALAC Hip Temporary Prosthesis	DePuy Orthopaedics, Inc., a Johnson & Johnson Company	This device is indicated for use as a short-term total hip replacement (THR) in patients who need a two-stage procedure to treat a confirmed infection of their THR and where vancomycin and tobramycin are the most appropriate antibiotics for treatment of the infection based on the susceptibility pattern of the infecting microorganism(s).
H990013 21-Feb-2001 01M-0201	Composite Cultured Skin (CCS)	Ortec International, Inc. New York, NY 10032	For use in patients with mitten hand deformities due to Recessive Dystrophic Epidermolysis Bullosa (RDEB) as an adjunct to standard autograft procedures (i.e., skin grafts and flaps) for covering wounds and donor sites created after the surgical release of hand contractures (i.e., "mitten" hand deformities).

H000001 10-Jan-2001 010M-006	JOMED JOSTENT® Coronary Stent Graft	JOMED AB	For Use in the treatment of free perforations, defined as free contrast extravasation into the pericardium, in native coronary vessels or saphenous vein bypass grafts > 2.75 mm in diameter.
H990012 11-May-2000 00M-1354	TAS Ecarin Clotting Time Test	Cardiovascular Diagnostics, Inc.	To be used to determine the anticoagulant effect of recombinant hirudin (r-hirudin) during cardiopulmonary bypass in patients who have heparin induced thrombocytopenia (HIT).
H990014 31-Mar-2000 00M-1451	Enterra™ Therapy System (formerly named Gastric Electrical Stimulation (GES) System	Medtronic, Inc.	For the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.
H990008 09-Mar-2000 00M-1228	Telescopic Plate Spacer (TPS) Spinal System	Interpore Cross International	To replace normal body structures following a vertebrectomy/corpectomy of the spine for metastatic disease in the cervical and/or cervico-thoracic spine (C3-T2). The TPS Spinal System implants are intended to correct spinal alignment and stablize the spinal operative site during fusion. TPS Spinal System implants attach to the spine anteriorly by means of their trapezoidal shape and by screws joined with a plate and spacer component.
H990011 01-Feb-2000 00M-0599	CardioSEAL® Septal Occlusion System	Nitinol Medical Technologies, Inc	For closure of a patent foramen ovale (PFO) in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a patent

			foramen ovale and who have failed conventional drug therapy.
H980006 10-Dec-1999 99M-5539	TheraSphere®	MDS Nordion, Inc., Kanata, Ontario, Canada	For radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic arterial catheters.
H990007 07-Dec-1999 99M-5327	BioGlue®Surgical Adhesive	CryoLife, Inc.	For use as an adjunct in the surgical repair of acute thoracic aortic dissections.
H980007 30-Sep-1999 99M-4810	Shelhigh Pulmonic Valve Conduit Model NR-4000 with "No-React®" Treatment	Shelhigh, Inc.	For replacement of the diseased, damaged. or absent pulmonic artery in small children or infants up to age 4 years, with Transposition of the Great Arteries, Truncus Arteriosis, Tetrology of Fallot with associated cardiac anomalies or with Pulmonary Atresia, or replacement of failed conduits in young patients with accelerated conduit failure.
H990005 28-Sep-1999 99M-4763	CardioSEAL®Septal Occlusion System	Nitinol Medical Technologies, Inc	For the treatment of patients with complex ventricular septal defects (VSD) of a significant size to warrant closure, but that, based on location, cannot be closed with standard surgical transatrial or transarterial approaches.
H990003 20-Sep-1999 99M-4619	Acticon™Neosphincter	American Medical Systems, Inc.	For the treatment of severe fecal incontinence in post-pubescent males and females who have failed, or are not candidates for, less invasive forms of

			restorative therapy.
H990004 08-Sep-1999 99M-4134	CardioSEAL® Septal Occlusion System	Nitinol Medical Technologies, Inc.	For the treatment of patients with complex single ventricle physiology who have undergone a fenestrated Fontan palliation procedure and require closure of the fenestration.
H980008 19-Feb-1999 99M-0255	VOCARE® Bladder System	NeuroControl Corporation Valley View, OH 44125	For the treatment of patients who have clinically complete spinal cord lesions (ASIA Classification) with intact parasympathetic innervation of the bladder and are skeletally mature and neurologically stable, to provide urination on demand and to reduce post-void residual volumes of urine. Secondary intended use is to aid in bowel evacuation
H980005 28-Dec-1998 99M-0150	VOCARE® Bladder System	NeuroControl Corp. Valley View, OH 44125	For the treatment of patients who have clinically complete spinal cord lesions (ASIA Classification) with intact parasympathetic innervation of the bladder and are skeletally mature and neurologically stable, to provide urination on demand and to reduce post-void residual volumes of urine.
H980002 28-Sep-1998 98M-0895	Avanta Proximal Interphalangeal (PIP) Finger Prosthesis	Avanta Orthopaedics, Inc	For use in arthroplasty of the PIP joint when either the: (1) patient is in need of a revision of failed PIP prosthesis(es); or (2) patient expects to place his/her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and

			post traumaic arthritic PIP joint.
H970005 30-Apr-1998 98M-0452	Perma-Flow® Coronary Graft, Model 2C10	Possis Medical, Inc. Minneapolis, MN 55433	For single or multiple vessel coronary artery bypass in patients who are receiving coronary bypass grafting but who have inadequate autologous conduit to complete the required revascularization.
H970004 06-Apr-1998 98M-0435	Excorim® Immunoadsorption System	Cobe BCT., Inc. Lakewood, CO 80215	For use in the treatment of patients with hemophhilia A and B who have Factor VIII or Factor IX inhibitor titers above 10 Bethesda Units/ml (BU/ml). The purpose of the system is to lower the inhibitor levels so that routine clotting factor rerplacement therapy can be considered. It may be used in an acute setting (to control bleeding during an acute hemmorrhage or for emergency surgery) or as a preventive measure to prepare patients for elective surgery.
H970003 16-Dec-1997 98M-0163	Urostim	William E. Kaplan, M.D. and Ingrid Richards, R.N., MSN Chicago, IL 60614	For use in children for the treatment of neurogenic bladder disease secondary to spina bifida
H970001 30-Sep-1997 98M-0164	King's College Hospital (KCH) Fetal Bladder Drainage Catheter	Rocket Medical PLC England	For urinary tract decompression following the diagnosis of post-vesicular obstructive uropathy in fetuses 18 to 32 weeks gestational age
H960001 14-Feb-1997 97M-0124	Harrison Fetal Bladder Stent Set (Lowery Modification)	Cook OB/GYN® Spencer, IN 47460	For fetal urinary tract decompression following the diagnosis of fetal post-vesicular obstructive uropathy in fetuses of 18

to 32 weeks gestational age

Other HDE Information

- Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers; Final Guidance for Industry Text or PDF Text PDF
- HDE Checklist for Filing Decisions Text or PDF Text PDF

Back to Device Evaluation Page

Updated November 24, 2003

---

fax header sheet

Rhode Island Department of Human Services
Center for Child and Family Health
600 New London Avenue
Cranston, Rhode Island 02920

fax: (401) 462-6353 main fax

Date: 1/13/06 Fax: 454-7752

To: Gilson DaSilva
(BCBS of RI)

Message: Benefits Clarification

This fax header sheet is page one (1) of _____ pages.

Confidentiality Statement: This transmission may contain confidential health information that is legally privileged. This information is intended only for the use of the individuals or entities listed above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately and arrange for the return or destruction of these documents.

To reach the **Center for Child and Family Health**, please call: (401) 462-2501.

Sender's name: Tricia Leddy **Phone:** 462-6346

Sender's title: _____

Faxed by: _____ Date & Time _____

fax header sheet

Rhode Island Department of Human Services
Center for Child and Family Health
600 New London Avenue
Cranston, Rhode Island 02920

fax: (401) 462-6353 main fax

Date: 1/13/06 Fax: 732-7210

To: Patrice Cooper
(United Health Care)

Message: Benefits Clarification

This fax header sheet is page one (1) of 4 pages.

To reach the **Center for Child and Family Health**, please call: (401) 462-2501.

Sender's name: Tricia Healdy **Phone:** 462-6346

Sender's title: _____

Faxed by: _____ Date & Time _____

fax header sheet

Rhode Island Department of Human Services
Center for Child and Family Health
600 New London Avenue
Cranston, Rhode Island 02920

fax: (401) 462-6353 main fax

Date: 1/13/06 Fax: 459-6175

To: Ron Barnett
(NHPRI)

Message: Benefits Clarification

This fax header sheet is page one (1) of 14 pages.

To reach the **Center for Child and Family Health**, please call: (401) 462-2501.

Sender's name: Tricia Healey **Phone:** 462-6346

Sender's title: _____

Faxed by: _____ Date & Time _____

TRANSMISSION VERIFICATION REPORT

TIME : 01/13/2006 16:25
NAME : CCFH
FAX : 4626353
TEL : 4626353
SER.# : BROJ3J674978

DATE,TIME	01/13 16:21
FAX NO./NAME	94596175
DURATION	00:04:22
PAGE(S)	14
RESULT	OK
MODE	STANDARD ECM

TRANSMISSION VERIFICATION REPORT

TIME : 01/13/2006 16:33
NAME : CCFH
FAX : 4626353
TEL : 4626353
SER.# : BROJ3J674978

DATE,TIME	01/13 16:27
FAX NO./NAME	97327210
DURATION	00:06:22
PAGE(S)	14
RESULT	OK
MODE	STANDARD ECM

TRANSMISSION VERIFICATION REPORT

TIME : 01/13/2006 16:38
NAME : CCFH
FAX : 4626353
TEL : 4626353
SER.# : BROJ3J674978

DATE,TIME	01/13 16:34
FAX NO./NAME	94547752
DURATION	00:03:50
PAGE(S)	14
RESULT	OK
MODE	STANDARD ECM